## APPENDIX A: CLAIMS PENDING PRIOR TO

RESPONSE TO OFFICE ACTION DATED JULY 25, 2006 FOR 09/776,250

## 13.-20. CANCELED

- 21. (Original) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient:
- (a) on the first day of treatment, a composition comprising autologous tumor cells or tumor cell extracts which corresponds to from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells free of any adjuvant;
- (b) four to seven day after initiation of the treatment an immunomodulatory agent that potentiates protective anti-tumor immunity or inhibits immune suppression or both; and
- (c) at least one additional composition comprising autologous tumor cells or tumor cell extracts.
- 22. (Original) The method of claim 21, in which the immunomodulatory compound is cyclophosphamide.
- 23. (Original) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient:
- (a) on the first day of treatment, a composition comprising a haptenized autologous tumor cell or tumor cell extract which corresponds to from about  $2 \times 10^5$  to  $2.5 \times 10^6$  tumor cells free from any adjuvant;
  - (b) four to seven days after initiation of the treatment, cyclophosphamide; and

- (c) at least one week after initiation of the treatment, a composition comprising an adjuvant and a haptenized autologous tumor cell or tumor cell extract which corresponds to from about  $2 \times 10^5$  to about  $1 \times 10^7$  tumor cells.
- 24. (Amended) The method in claim 23, in which the adjuvant is *Bacille Calmette-Guerin*.
- 25. (New) The method of claim 21, wherein the tumor cells or tumor cell extract is haptenized.
- 26. (New) The method of claim 21, wherein the tumor cells or tumor cell extract is a mixture of haptenized and non-haptenized tumor cells or tumor cell extract.
- 27. (New) The method of claim 21, wherein at least one of the tumor cell or tumor cell extract composition is haptenized.
- 28. (New) The method of claim 26, where the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'- (5-sulfonic 1 -naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.
  - 29. (New) The method of claim 28, in which the hapten is dinitrophenyl.
- 30. (New) The method of claim 21, wherein the tumor cell extract comprises tumor cell membrane components.
- 31. (New) The method of claim 21, wherein the tumor cell extract comprises tumor cell polypeptides.

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- 32. (New) The method of claim 21, wherein the tumor cells or tumor cell extracts originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.
  - 33. (New) The method of clam 21, wherein the tumor is melanoma.
  - 34. (New) The method of claim 21, wherein the tumor is ovarian cancer.
- 35. (New) The method of claim 21, wherein the tumor cell or tumor cell equivalents are rendered incapable of growth or multiplication *in vivo*.
- 36. (New) The method of claim 31, wherein the tumor cell or tumor cell equivalents are rendered incapable of growth or multiplication *in vivo* by irradiation.
- 37. (New) The method of claim 31, wherein the tumor cells or tumor cell equivalents are rendered incapable of growth or multiplication *in vivo* by haptenization.
- 38. (New) The method of claim 21, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.
- 39. (New) The method of claim 21, wherein the mammalian patient is a domestic pet or livestock.
- 40. (New) The method of claim 21, wherein the immunomodulatory agent is administered 5 to 7 days after initiation of the treatment.
  - 41. (New) The method of claim 21, wherein the patient is a human.
- 42. (New) The method of claim 23 wherein the mammalian patient is a domestic pet or livestock.
- 43. (New) The method of claim 23, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin
  - 44. (New) The method of claim 23, wherein the patient is a human.

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- 45. (New) The method of claim 23, wherein the immunomodulatory agent is administered 5 to 7 days after initiation of the treatment.
- 46. (New) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient a composition comprising a haptenized or a non-haptenized tumor cell comprising from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cells or tumor cell equivalents per dose, without any adjuvant, wherein the tumor cells or cell equivalents are conjugated to a hapten, and rendered incapable of growth or multiplication in vivo, prior to a second composition comprising an adjuvant and a tumor cell, which second composition contains from about  $2 \times 10^5$  to about  $2.5 \times 10^6$  tumor cell or tumor cell equivalents, wherein the tumor cell or tumor cell equivalents are conjugated to a hapten.
- 47. (New) The method of claim 46, wherein the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.
  - 48. (New) The method of claim 46, wherein the tumor is melanoma.
  - 49. (New) The method of claim 46, wherein the tumor us ovarian cancer.
- 50. (New) The method of claim 46, wherein the adjuvant is selected from the group consisting of *Bacille-Calmette-Guerin*, Q-21, and detoxified endotoxin.
- 51. (New) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient:
- (a) on the first day of the treatment, a composition comprising autologous tumor cells, which corresponds to from about  $2x10^5$  to about  $2.5x10^6$  tumor cells, free of any adjuvant;

- (b) four to seven days after initiation of the treatment, an immunomodulatory agent that potentiates protective anti-tumor immunity or inhibits immune suppression, or both; and
  - (c) at least one additional composition comprising autologous tumor cells.
  - 52. (New) The method of claim 51, wherein the tumor is melanoma.
  - 53. (New) The method of claim 51, wherein the tumor is ovarian cancer.
- 54. (New) The method of claim 51, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.
- 55. (New) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which, method comprises administering to the patient:
- (a) on the first day of treatment, a composition comprising a haptenized autologous tumor cell which corresponds to from about  $2 \times 10^5$  to  $2.5 \times 10^6$  tumor cells free from any adjuvant;
  - (b) four to seven days after initiation of the treatment, cyclophosphamide; and
- (c) at least one week after initiation of the treatment, a composition comprising an adjuvant and a haptenized autologous tumor cell which corresponds to from 2 x  $10^5$  to 1 x  $10^7$  tumor cells.
  - 56. (New) The method of claim 55, in which the adjuvant is *Bacille Calmette-Guerin*.